

Application No. 10/616,055

REMARKS

This reply is in response to the non-final Office Action dated August 21, 2006. Claims 1-69 are pending. Claims 9, 10, 32, 33, and 58 have been withdrawn, pending allowance of linking claims, in which case their re-entry and allowance is requested. Claims 1-8, 11-31, 34-57, and 59-68 stand rejected. Claims 19 and 63 are amended to delete the term "air".

The Application was filed as a continuation, but the Office Action disputes the support of certain of the claims such that the Office Action denies the claim to priority of the parent. Specifically, the Office Action (at page 2) denies that "air" as claimed, is absent from the specification. This is understood to be the sole basis for this objection; please clarify if there are other reasons. On this basis, the term "air" has been deleted where it occurs in the claims (claims 19 and 63) solely to expedite prosecution. Acknowledgement of the priority claim for the parent application is requested.

The examined claims were rejected for lack of enablement and lack of antecedent basis on the grounds that the term "air" was not in the specification. The deletion of this term is believed to make these rejections moot.

Claims 1-8, 11-31, 34-37, and 59-69 were rejected under 35 U.S.C. §103(a) based on U.S. 5,843,743 (Hubbell) and U.S. 4,948,575 (Cole). No prior art was disclosed in the Office Action with respect to the claimed volumetric expansion of at least about 20% (independent claim 53) or 50% (independent claims 1 or 41) after swelling with physiological fluid. Instead, the Office Action (at page 4) argued that such expansion could be obtained by routine experimentation, with reference to *Application of Boesch* 617 F.2d 272, 205 U.S.P.Q. 215 (C.C.P.A. 1980).

Boesch stands for the proposition that discovery of an optimum value of a result effective variable in a known process is ordinarily within skill of the art. An examination of *Boesch* sheds light on what is meant by a result effective variable. In *Boesch*, each of the ranges of

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constituents in the patent applicants' claimed alloys **overlapped ranges disclosed by the prior art** disclosed in two publications. 617 F.2d 272, 275 (see first sentence under "Opinion"). The court's analysis stated that "Considering, also, that the composition requirements of the claims and the cited references overlap, we agree with the Solicitor that the prior art would have suggested 'the kind of experimentation necessary to achieve the claimed composition, including the proportional balancing described by appellants' N v equation.' This accords with the rule that discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. In re Antonie, 559 F.2d 618, 195 USPO 6 (Cust. & Pat.App.1977)" 617 F.2d 272, 276. Thus *Boesch* requires two factors: (1) there is prior art that discloses the variable over the range that is claimed and (2) the claimed variable is recognized as achieving the beneficial result, i.e., it is a result-effective variable. These facts explain why the MPEP places *Boesch* in "§2144.05 Obviousness of Ranges".

What is lacking in the Office Action is (1) evidence that the claimed expansion is disclosed in the prior art and (2) that the claimed expansion is a result-effective variable. The case cited in *Boesch*, *In Re Antonie* admonishes the Patent Office for this type of error: "The PTO and the minority appear to argue that it would always be obvious for one of ordinary skill in the art to try varying every parameter of a system in order to optimize the effectiveness of the system **even if there is no evidence in the record that the prior art recognized that particular parameter affected the result**. As we have said many times, **obvious to try is not the standard** of 35 U.S. C. §103. Disregard for the unobviousness of the results of "obvious to try" experiments disregards the "invention as a whole" concept of §103, and overemphasis on the routine nature of the data gathering required to arrive at appellant's discovery, after its existence became expected, overlooks the last sentence of §103". *In Re Antonie* 559 F.2d 618, 620, 195 U.S.P.Q. 6 (C.C.P.A. 1977) (citations omitted, emphasis added).

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It is respectfully submitted that there is no prima facie case of obviousness because the Office Action does not suggest that the prior art references disclose the claimed expansion, nor does it indicate that expansion is a result-effective variable, e.g., why varying the claimed expansion would be desirable, or what optimization would be taking place by varying it. Therefore this rejection must be withdrawn.

Moreover, the Office Action indicated that "placement in a lumen" is merely an intended use. Respectfully, this characterization is not a fair reading of the claims. In the first place, no "placement in a lumen" is claimed. What is claimed in the independent claims is "a shape to occlude the lumen or void upon swelling from exposure to a fluid from the body after implantation in the lumen or void" (Claim 1) or "a shape and a substantially less than equilibrium level of hydration for undergoing a volumetric expansion of at least about 50% in physiological fluid to occlude the lumen or void created by the percutaneous catheter puncture after swelling with fluid from the body" (Claim 41) or "a shape for passage through an inner diameter of a catheter or hollow needle into the body" (claim 53). The claimed shapes relate to, among other things, structures that can occlude the lumen or void. The independent claims were amended without narrowing to clarify that what is claimed is an "implant" before implantation.

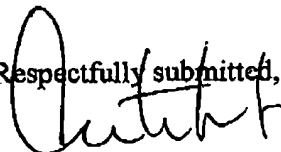
Further, the cited references fall short of providing all of the claimed elements. Hubbell and Cole do not disclose the claimed expansion of hydrogels or the claimed hydrogel having a substantially less than equilibrium level of hydration that is swellable with physiological fluid. For instance, Cole discloses making a foaming material on a wound area but does not disclose the claimed hydrogel having a substantially less than equilibrium level of hydration that is swellable with physiological fluid. Nor is there guidance in Hubbell or Cole for creating a desired degree of expansion, or the claimed amount of expansion. Nor is there guidance in Hubbell or Cole for choosing to make materials with the expansion that is claimed in combination with the shapes and structures that are claimed.

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Moreover, there is no motivation to combine Cole and Hubbell. The Office Action points to Cole as disclosing "prolonging the healing process of a wound" as a motive. Taken at face value, it would seem that "prolonging the healing process of a wound" would be a good reason *not* to use Cole since most artisans presumably wish to *accelerate* wound healing. What Cole actually teaches at column 2 lines 58-62 is that its "novel nonfibrous wound dressing" releases "easily from wound tissue" without causing "further damage to the wound and prolonging the healing process". This passage suggests that the value of the dressing is at least in part attributable to the use of alginate, so that using the foaming-based approach of Cole with the materials of Hubbell is mere speculation and not based in the prior art.

Furthermore, there is no motivation to combine Cole and Hubbell to make the claimed invention because Cole teaches away from having a substantially less than equilibrium level of hydration for undergoing a volumetric expansion to occlude a lumen or void after swelling with a fluid from the body. Cole teaches that "If the dressing swells upon the absorption of fluids, this lack of dimensional stability may severely undercut the utility of these dressing for packing deep, heavily exuding wounds." Cole column 2 lines 45-48. Consequently, "When applied in or on a wound, the foaming action gently expands the dressing material conforming it to the shape of the cavity in, or the surface on, which it is applied. The dressing material subsequently cures to a **dimensionally stable hydrogel foam which exactly fits the wound.**" Cole, column 3, lines 19-25, emphasis added. The dimensionally stable non-expanding hydrogels taught by Cole are what is **not claimed** - this teaching points the artisan away from what is claimed.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,


Curtis B. Herbert, Ph.D., Esq.
Registration No. 45,443

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Customer No. 62274
Dardi & Associates, PLLC
US Bank Plaza, Suite 2000
220 South 6th Street
Minneapolis, Minnesota 55402
Telephone: (612) 605-1038